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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,366	05/16/2001	Richard A. Brauckman	TGXX-1005US	3214

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EXAMINER	
RAMANA, ANURADHA	

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/858,366	BRAUCKMAN ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-31,33 and 35-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7-14,21-31,33,35,36,38 and 39* is/are allowed.

6)☒ Claim(s) *1-6,15-18,20 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed as a list of co-pending U.S. Patent Applications, on page 10 of the response submitted by the Applicants on February 23, 2004, fails to comply with 37 CFR 1.98(d). 37 CFR 1.98(d) requires that copies of pending US applications be submitted for consideration by the Office.

Further, the information disclosure statement fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p).

For proper consideration, the Applicants must submit an information disclosure statement in compliance with 37 CFR 1.97 and 1.98.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter "sufficient bond strength ..... body," that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is the Examiner's position that "sufficient bond strength" cannot be determined without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to claim 1, it is unclear what "normal conditions of use" are.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. (US 5,199,939).

Dake et al. disclose a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake et al., to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of radioactive segment 30 to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable Dake et al. in view of Hess (US 5,302,168).

Regarding claim 2, Dake et al. do not disclose a balloon catheter body wherein the radioactive source is bonded to an exterior surface of the catheter body.

Regarding claim 5, Dake et al. do not disclose a retractable sheath.

Hess discloses a device 10 for radiation treatment including a balloon catheter with a balloon or "expandable portion" 36 with radioactive elements or source 38 attached or "bonded"

to a balloon 36 wherein when the balloon 36 is expanded in the vicinity of the lesion or treatment site, the radioactive source 38 is forced into contact with the treatment site (col. 3, lines 20-45 and Figures 1, 2 and 4).

Hess also discloses an embodiment of device 10 including a retractable sheath (wire wound for radiation containment or shielding) or shield 24 that can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site (col. 3, lines 26-40).

Regarding claim 2, it would have been obvious to one of ordinary skill in the art to substitute a balloon catheter as, for example, taught by the Hess reference for the Dake et al. device wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in the claimed device.

Regarding claim 5, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath around the Dake et al. device, as taught by Hess, for shielding the radiation source.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dake et al. in view of Carden, Jr. (US 5,405,309).

Dake et al. do not disclose carrier-free palladium 103 as the radiation source.

Carden, Jr. teaches carrier-free palladium 103 (Pd-103) as a safe radiation source for therapeutic purposes (col. 1, lines 40-45, col. 4 and col. 5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free Pd-103 as the radiation source in the device of Dake et al. for enhanced safety.

Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie (US 5,282,781), in view of Hess, further in view of Dake et al.

Liprie discloses an elongate, flexible carrier 10 with a radioactive source 25 housed within a cavity in the distal end of carrier 10, the distal end of carrier 10 having a plug 27 to provide access to the cavity. Liprie also discloses that carrier 10 is placed within an elongate

flexible catheter body 75 wherein catheter body 75 provides a path to flexible carrier 10 from a point external to the body to a tumor site (Figs. 1, 7, col. 5, lines 54-68, col. 6, lines 1-15, col. 8, lines 67-68, col. 9, line 1, col. 10, lines 48-52, col. 16, lines 64-68 and col. 17, line 1).

Liprie does not disclose a retractable sheath made of radiation shielding material surrounding flexible carrier 10.

Further, Liprie does not disclose a radiation does in an amount of about 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive source.

Hess teaches a radiation device 10 having a retractable sheath 24 surrounding a radioactive dose means 30 to provide a measure of shielding for the radioactive dose means wherein sheath 24 can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site (col. 3, lines 26-40 and col. 4, lines 13-23).

Dake et al. teach a catheter 10 for endoluminal radiation treatment having an elongated flexible, hollow body 12 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the device of Liprie for radiation shielding as taught by Hess.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source 25 in the device of the combination of Liprie and Hess, to provide 10 microcuries to about 100 curies per centimeter length of source 25, as taught by Dake et al., for the purpose of treating restenosis. Further, it would have been obvious to one of ordinary skill in the art to have provided a radiation source in the device of the combination of Liprie, Hess and Dake et al. to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claims 17, 18 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over further over Liprie, in view of Hess and Dake et al., further in view of Leavitt et al. (US 6,352,682).

Leavitt et al. teach a polymer depot or radioactive source wherein a radioactive material is immobilized in a biodegradable polymeric material that can be in the form of a gel (col. 1, lines 49-51, col. 2, lines 39-43, col. 3, lines 44-48 and col. 4, line 52) as a source of radiation.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source within a cavity in the distal section of the body of the device of the combination of Liprie, Hess and Dake et al. wherein the radioactive source is immobilized in a polymeric material in the form of a gel as a source of radiation as taught by Leavitt et al.

Regarding claim 37, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected a biodegradable polyester polymeric material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, namely a suitable polymeric material, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie in view of Hess and Dake et al. as applied to claim 15, further in view of Carden, Jr.

See discussion for claim 6.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided carrier-free palladium-103, as taught by Carden, Jr., within a cavity in the distal section of the device of the combination of Liprie, Hess and Dake et al. for enhanced safety.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 or 2 or 3 or 14 (incorrectly numbered 13) of copending Application No. 09/858,816 (US 20030204125 or '125) in view of Hess.

This is a provisional obviousness-type double patenting rejection.

Claims 1 or 2 or 3 or 14 ('125) separately have all the elements of claims 1-3 and 5 except that the radiation delivery device is a catheter.

Hess teaches a radiation delivery device which is a catheter body having a flexible or deformable substrate or balloon 36 and supplies the missing element.

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15 (incorrectly numbered 14) of copending Application No. 09/858,816 (US 20030204125 or '125) in view of Hess.

This is a provisional obviousness-type double patenting rejection.

Claim 15 ('125) has all the elements of claim 6 except that the radiation delivery device is a catheter.

Hess teaches a radiation delivery device which is a catheter body having a flexible substrate or balloon 36 and supplies the missing element.

Claims 1 and 3-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending application 10/010,250 (US 20020147379) or '379 in view of Dake et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 5 of '379 has all the elements of claim 1 except for the claimed radiation amount of 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive portion.

Dake et al. teaches a catheter or tube10 with a radioactive means or "source" 14 in radioactive segment 30 of the distal section 20 of the catheter wherein the radioactive means 14 can be any shape and can be placed onto or into body 12 or manufactured into the material of body 12 and provides radiation in an amount from about 10 microcuries to about 100 curies per centimeter length of the radioactive segment 30 (Figures 1 and 9, col. 2, lines 49-54, col. 3, lines 58-68, col. 4, lines 1-8 and lines 34-36, col. 5, lines 19-22 and line 68 and col. 6, lines 1-5).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radioactive source, as taught by Dake et al., in the '379 device to provide radiation in an amount of 0.5 microcuries to about 300 curies per centimeter length of radioactive segment 30 to treat restenonis since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claim 5 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/010,250 (US 20020147379 or '379) in view of Dake et al. and Hess.

Claim 5 ('379) does not disclose a retractable sheath.

Hess teaches a radiation device 10 having a retractable sheath 24 surrounding a radioactive dose means 30 to provide a measure of shielding for the radioactive dose means wherein sheath 24 can be drawn back when the radiation source 30 in the distal end 18 of device 10 is positioned directly proximate to a treatment site (col. 3, lines 26-40 and col. 4, lines 13-23).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a retractable sheath in the device of the combination of claim 5 ('379) and Dake et al., for radiation shielding as taught by Hess.

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/010,250 (US 20020147379 or '379) in view of Dake et al. and Carden, Jr.

Claim 5 ('379) has all the elements of claim 6 except for the claimed radiation amount of 0.5 microcuries to about 300 microcuries per centimeter length of the radioactive portion and carrier-free palladium 103.

Dake et al. and Carden, Jr. supply the missing elements.

Allowable Subject Matter

Claims 7-14, 21-31, 33, 35, 36 and 38-39 are allowed.

Response to Arguments

Applicants' arguments submitted under "REMARKS," in the response filed on July 31, 2003, with respect to the rejections of claims 1-18, 20-31 and 33-35 have been fully considered but are not persuasive with respect to claims 1-6, 15-18 and 20.

Upon further consideration, new grounds of rejection have been made with Dake et al. as the base reference for claims 1-6. Dake et al. is more pertinent to Applicants' claimed invention in light of the 112 para 1 rejections made in this action. The Examiner sincerely apologizes for not making this determination in the earlier actions.

Applicants' arguments with respect to claims 15-18 and 20 have been considered but are moot in view of the revised rejection of this claim made in this Office Action. It is the Examiner's position that hollow tubing 12 of Liprie only contains radioactive source 25 but does not serve to prevent radiation exposure by acting as a radiation shield.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 17, 2004

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